IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES LLC AND EDWARDS LIFESCIENCES PVT, INC.,	)	
Plaintiffs	)	
v.	)	C.A. No. 12-023-GMS
MEDTRONIC COREVALVE LLC, MEDTRONIC CV LUXEMBOURG S.A.R.L., MEDTRONIC VASCULAR GALWAY LTD., MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,	)	
Defendants.	)	

MEDTRONIC'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR A NEW TRIAL OR ALTERNATIVELY TO AMEND OR ALTER THE JUDGMENT

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Dated: May 14, 2014

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I. INTRODUCTION

Edwards' opposition to Medtronic's new trial motion is legally unsound and factually inaccurate. While there were many rulings that warrant a new trial, two in particular stand out given the record before this Court.

First, it cannot be legitimately disputed that the CoreValve device cannot infringe any asserted claim because it cannot fit through a 5.7 mm introducer.[1] ***Edwards has admitted this fact***, yet that factual admission was improperly excluded from the jury, and Edwards was allowed to argue before this tribunal the exact opposite of what it asserted in Europe.

Second, both Drs. Cribier and Buller ***admitted*** without objection that the full scope of the claims is not enabled. Yet, Edwards convinced this Court to prevent Medtronic from discussing that evidence during closing arguments. Despite that, Edwards boldly states that "[a]s the jury found, the '825 Patent teaches the full scope of the claimed invention." Edw. Br. at 10. But Medtronic was not allowed to fully address all of the evidence before the jury reached its verdict.

Because this dispositive, indisputable evidence of non-infringement and invalidity was kept from the jury, a new trial must be awarded if the Court does not grant judgment as a matter of law in Medtronic's favor.

II. ARGUMENT

For all the reasons set forth in Medtronic's Opening Brief, and in its briefs in support of its renewed JMOL motion, the verdict is against the weight of the evidence and is a miscarriage of justice. If judgment is not entered in Medtronic's favor, a new trial must be awarded.

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[1] As set forth in Medtronic's briefs in support of its renewed JMOL motion, Edwards' failure to present any evidence with respect to the "recoil force" limitation also demonstrates that the verdict is against the weight of the evidence and provides additional grounds for a new trial.

A. Edwards' Misrepresentations Regarding the "18 French Arterial Introducer" Limitation Necessitate a New Trial.

The plain language of the asserted claims limits the scope to devices capable of introduction through an "18 French arterial introducer," which the Court properly construed as limited to a diameter of 5.7 mm or less. Under this construction, Medtronic does not infringe because the CoreValve does not fit, as the Court recognized on the first day of trial:

> I don't think there is going to be much dispute that the model as constructed doesn't fit through 5.7 millimeter hole. If I were to accept your construct, that would be the end of this, wouldn't it? . . . I can look at that and see it doesn't go through. There is not going to be a disagreement among the experts.

Trial Tr. 12:12-23.

Medtronic was not allowed to present this straightforward, dispositive non-infringement case to the jury: "I am not going to let you do it." Trial Tr. 13:1. Responsibility for this error lies directly with Edwards, because Edwards misled the Court into believing Medtronic had failed to address this issue earlier: "If this argument had been properly teed up a long time ago, we might be in an entirely different place today." Trial Tr. 13:7-9.

But Medtronic has always asserted it does not infringe under this Court's proper construction, and has always asserted that the limitation requires the ***entire device*** to pass through such an introducer. ***Edwards***, however, sought to re-construe the claim in its expert report after realizing Medtronic's proposed construction was fatal to its infringement assertion. Prior to that time, Edwards agreed in multiple government proceedings that "18 French" limited the size of the entire device to be delivered.

First, during prosecution of the parent to the '825 patent, Edwards told the PTO that effectively identical language ("***the stent*** being collapsible to a collapsed diameter of 5.7 millimeters or less") limits the size of ***the entire device***:

> There is no teaching or suggestion in the cited references regarding a prosthetic valve assembly comprising a stent, a valvular structure and an internal cover, wherein ***the entire prosthetic valve assembly is collapsible to a diameter of 5.7 mm or less for advancement through an introducer and into a patient's vasculature via a catheterization technique***.[2]

D.I. 185, DTX 322 at 1068 (emphasis added).

Second, Edwards argued to the European Patent Office that effectively identical language in a counterpart patent limited the size of the complete device: "***that the frame is compressible*** to an external diameter ***does not mean anything else than that in fact the entire prosthetic valve assembly is compressible*** to said diameter." D.I. 135, Ex. 2 ¶ 42 (emphasis added).

Edwards also told this Court the "18 French" limitation applied to the device, not just the frame: "an '18 French arterial introducer' is sized to permit ***delivery of a device*** with an outside diameter of 18 French." D.I. 53 at 12 (emphasis added). Only later, contradicting three admissions in three separate government proceedings, did Edwards serve Dr. Buller's report, in which he raised an untimely claim construction argument: "Medtronic's proposed ***construction of an '18 French arterial introducer'*** is flawed . . . . Medtronic improperly applies ***the 18 French limitation*** to the entire 'prosthetic valve' as opposed to only the frame, which is all that the claim requires." D.I. 145, Ex. 3 ¶ 390 (emphasis added). Edwards ***never*** raised this new issue with this Court.

Medtronic, on the other hand, made two attempts to raise this issue with the Court, first in letter briefing requesting permission to move for summary judgment of non-enablement, D.I. 107 at 2, and second in a request to Edwards that the parties be permitted to file truncated letter briefs requesting permission to seek summary judgment based on the Court's claim construction

[2] Edwards' suggestion that, under the proper claim construction, it "would have had the opportunity to rely on the doctrine of equivalents" is meritless. *See* Edw. Br. at 5 n.6. Edwards is estopped from reliance on the doctrine of equivalents by its statements to the PTO.

order, which issued after the deadline to file such briefs. Medtronic then "properly teed up" this issue at the next available opportunity, when it informed the Court at the *in limine* stage that Edwards intended to offer expert testimony that was inconsistent with the plain language of the claims and the Court's claim construction order. D.I. 125, Ex. W ¶ 1(a).[3]

In response to Medtronic's *in limine* issue, Edwards mischaracterized the dispute as involving the construction of "frame," rather than "18 French arterial introducer." D.I. 131 at 74:3-5. It is clear, however, from Dr. Buller's report that the dispute relates to the introducer, not the frame. It has always been Medtronic's position that the thing to be introduced through the 5.7 mm introducer is the device itself, including the valve necessary for it to function.[4]

Misled by Edwards' mischaracterizations of the procedural history and the parties' dispute, the Court denied Medtronic's *in limine* motion. D.I. 139. But the Court did not re-construe the claims. During the trial, however, Edwards requested ***for the first time*** that the Court modify its claim construction. The Court granted Edwards' request and instructed the jury based on a construction that is not only erroneous and misguided but that was never advanced by Edwards until trial. Opening Br. at 3-4 (discussing Jury Instruction 3.2).

Because Edwards misled the Court, Medtronic was precluded from presenting dispositive evidence that its device does not infringe. Opening Br.at 3-5. Medtronic was also prevented from

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[3] In contrast to Medtronic's multiple efforts to put this issue before the Court, at no point did Edwards seek resolution of the dispute, notwithstanding the fact that it was Edwards that sought to inject an untimely claim construction argument. Tellingly, even at the *in limine* stage, Edwards did not seek to preclude Medtronic from presenting evidence that the entire device must be delivered through the 5.7 mm introducer. *See* D.I. 125, Ex. V. Edwards apparently intended to argue claim construction to the jury. Medtronic should not be punished for having brought this issue to the Court's attention.

[4] It has also always been Medtronic's position that the capsule that covers the CoreValve device must be included. Without this capsule, the self-expanding CoreValve device could not possibly be introduced using a catheterization technique.

presenting evidence that Edwards admitted in legal proceedings in Europe that Medtronic's device requires a 6.0 mm introducer and therefore cannot infringe any of the asserted claims, Opening Br. at 5-8, even though the Federal Circuit has repeatedly held that ***statements made before a foreign patent office are relevant*** if they are not related to unique aspects of foreign law, as is the case here. *See, e.g.*, *Apple Inc. v. Motorola, Inc.*, No. 2012-1548, -1549, at *36 (Fed. Cir. April 25, 2014). Finally, Medtronic was prevented from presenting evidence that the asserted claims are invalid because the patent does not enable a complete device that is capable of delivery through an 18 French arterial introducer.[5] Opening Br. at 8-9. And the case was then submitted to the jury based on an erroneous and misguided claim construction. *Id.* at 3-4.

A new trial is necessary to correct the multiple errors that resulted from Edwards' misrepresentation of the dispute regarding the "18 French arterial introducer" limitation.

B. A New Trial Is Necessary to Correct Edwards' Misrepresentations on Novelty and Non-Enablement of the "18 French Arterial Introducer" Limitation.

As discussed above, during prosecution Edwards affirmatively relied on the compressibility of the device to allow introduction into a patient's vasculature through a 5.7 mm introducer using a catheterization technique as a novel aspect of Dr. Cribier's alleged invention. Edwards then came before the jury and this Court with the exact opposite position, and continues to do so in its opposition brief. *See* Edw. Br. at 12. Edwards cannot escape the effect of its PTO statement—compressibility to enable introduction through a 5.7 mm introducer using a catheterization technique is what Edwards claimed was the novel aspect of the claims.

In addition, the development documents that were excluded by the Court irrefutably establish that introduction through a 5.7 mm introducer using a catheterization technique was the

[5] Even under the improper claim construction, exclusion of this evidence was error. Opening Br. at 8-9.

assertedly novel aspect of the claimed invention. As Dr. Cribier testified during his deposition:

> Now after that, ***with the engineers, we had to face the real world, and so we had to accept, you know, that the engineers made it in 24 French***. ***So it was more or less disappointing.*** But this is part of the game. You know, when you -- when you want to make something, you can have a dream, so ***at the time of the patent it was a dream. At the time of the experiment it was real life***, and so we had to make with it. So ***this is why it took several years, you know, to decrease by one, two French the -- the size of the sheath***. That's all.

D.I. 102, Ex. A at 180:2-12 (emphasis added).

The excluded evidence establishes that Dr. Cribier and his engineers were unable to build any device that could be delivered through an 18 French introducer for over a decade. This evidence directly rebuts Dr. Buller's testimony that "[t]here is nothing about this dimension that is in any sense an invention or is difficult to do." *See* Edw. Br. at 13. Exclusion of the development evidence that establishes that it was actually very difficult to get to 18 French was highly prejudicial to Medtronic.

More fundamentally, Edwards' argument that the development evidence is not relevant because SAPIEN does not practice the claims is contrary to the evidence upon which Edwards did rely on the enablement issue. In opposition to Medtronic's Renewed JMOL motion, Edwards asserts compressibility for introduction into a patient's vasculature through a 5.7 mm introducer using a catheterization technique was not novel based on prior art stents that were never intended for use as a heart valve. D.I. 212 at 30. For Edwards to simultaneously rely on prior art stents that come nowhere close to practicing the claims to support enablement while Medtronic is precluded from relying on the development history of the aortic valve that followed directly from Dr. Cribier's alleged invention is fundamentally unfair and improper. A new trial is required.

C. A New Trial Is Necessary to Permit Medtronic to Address the Full Scope Enablement Requirement.

The plain language of the asserted claims includes a range of sizes, because it expressly

includes any device "capable of being introduced through an 18 French arterial introducer." Since serving its initial invalidity contentions, Medtronic has asserted that the claims are invalid for failure to enable the full scope of this claim limitation. Opening Br. at 12. At trial, Dr. Cribier admitted that the claims are not enabled for anything below 14 French. Trial Tr. 317:25-318:4. Dr. Buller then admitted that (1) the claims have no lower limit, and (2) are not enabled at least at 10 French. Trial Tr. 656:18-21, 655:4-10. Yet Medtronic was prevented from addressing these admissions during closing arguments despite the fact that those admissions unequivocally render the claims invalid. This error requires a new trial.

It is implausible that Edwards failed to understand Medtronic's repeated assertions throughout discovery that the full scope of the claims was not enabled before Edwards' witnesses admitted the requisite facts at trial. Now, to avoid the inescapable conclusion that the claims are invalid, Edwards advances a nonsensical argument that the presence of dependent claims with a narrower scope means that claim 1 does not claim a range of sizes. Claim differentiation only means that claim 1 and claims 8 and 9 presumptively do not have the same scope. And consistent with that doctrine, the claims do not, because claim 1 includes devices that can be delivered through introducers up to and including 18 French, whereas 8 and 9 do not.

But it is fundamental that the scope of dependent claims 8 and 9 is necessarily contained in independent claim 1. So, it cannot be disputed that claim 1 claims devices capable of delivery through an 18 French introducer, which claims a range that includes devices capable of delivery through 16 and 14 French introducers, as well as through a 10 French introducer—devices Drs. Cribier and Buller admitted are not enabled.

D. A New Trial Is Necessary to Correct the Failure to Instruct the Jury on the Active Inducement Requirement of 35 U.S.C. § 271(f)(1).

The plain language of § 271(f)(1) requires proof that the alleged infringer "actively

induce the combination of such components outside the United States ***in a manner that would infringe*** the patent." 35 U.S.C. § 271(f)(1) (emphasis added). To support its position, Edwards quotes an unreported district court case that inserts a semi-colon into the clause—not the statutory language. But the statute plainly requires proof that the alleged infringer intended the combination to constitute an infringement. *See* Edw. Br. at 6.

Because the jury was not properly instructed on this requirement, a new trial is required.[6]

E. A New Trial Is Necessary to Correct Exclusion of Evidence Establishing the Safe Harbor Exemption.

The safe harbor of § 271(e) is a statutorily created exemption to infringement. It is not among the defenses to infringement, which are set forth in § 282(b). Because the safe harbor is an exemption, not a defense, Medtronic was not required to plead it.

Moreover, the safe harbor of § 271(e) was ***always*** in this case. First, Edwards never accused Medtronic's clinical studies of infringement. So any suggestion that Edwards was unaware the safe harbor exemption applied to this case is belied by its own actions. Second, Edwards joined this issue in its Pretrial Brief. Opening Br. at 15. While Edwards challenged the merits of Medtronic's assertion that the continued access study was exempt under § 271(e), Edwards never raised any waiver argument.

It was Edwards' responsibility to describe the scope of its infringement allegations. Tellingly, Edwards never asserted infringement regarding Medtronic's continued access program in its interrogatory response. D.I. 88, Ex. I at 4; D.I. 78, Ex. 27. Nor did Edwards identify it in its initial infringement contentions. D.I. 78, Ex. 11. Instead, Edwards accused Medtronic's

[6] As fully set forth in Medtronic's briefs in support of its renewed JMOL motion, in addition to the improper instruction, the verdict is against the weight of the evidence as to §§ 271(f)(1) and (2) , providing additional grounds for a new trial.

continued access study for the first time in its damages expert report. D.I. 156, Ex. C. Edwards' suggestion that Medtronic should have informed Edwards of the statutory exemption's application to continued access ***before*** that activity was accused of infringement is nonsensical. *See* Edw. Br. at 14.[7]

Medtronic was not required to plead the safe harbor exemption, and it was not permitted to provide an evidentiary basis for its application. Medtronic is entitled to a new trial.

F. Remittitur or a New Trial on Damages Is Necessary.

The Court properly determined that Edwards is not entitled to collect damages based on the lost profits of non-parties. The jury's award of $103 million that was contrary to that instruction remains legally erroneous.

Edwards, however, refuses to accept that the jury's award was erroneous, and its attempt to distinguish the law is unavailing. As an initial matter, *Rite-Hite* is not "the case most applicable to this litigation." *See* Edw. Br. at 18. *Rite-Hite* involved a party and its wholly-owned sales organizations, in contrast to this case, where sister entities are involved as was the case in *Poly-America*. *Compare Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1542 (Fed. Cir. 1995), *with Poly-America, L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004). Edwards is also incorrect when it claims, *in italics*, that the Federal Circuit found that the patent owner would have been entitled to lost profits. *See* Edw. Br. at 18. To the contrary, the *Rite-Hite* court merely held that the patent owner "has not persuaded us that the court's decision was erroneous."

[7] Edwards continues to misrepresent the state of discovery. *See* Edw. Br. at 15 n.16. Medtronic did provide a witness on continued access sales, as Edwards admits. Edwards' accusation that Medtronic did not provide a witness for the "factual basis for any defense under 35 U.S.C. § 271(e)(1) or (f)" is therefore disingenuous since continued access is the factual basis for the exemption under § 271(e)(1). Medtronic's objection that the topic sought information not relevant to any claim or defense was based on Edwards' failure to assert a claim under § 271(f), which was not added until after the close of discovery. *See* D.I. 110.

56 F.3d at 1555.

Rite-Hite does not address when a patent owner can collect lost profits of a non-party. *Poly-America* and *Mars*, on the other hand, do address the issue, and set forth a clear rule that precludes recovery here: "a patent holder is not entitled to recover under a lost profits theory as a result of sales lost by a sister corporation, absent a showing that the patent holder *itself* had lost profits." *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1365 (Fed. Cir. 2008) (citing *Poly-America*, 383 F.3d at 1311).

Edwards' claim that "the issue of control over the sale/manufacture of the relevant products and the motivation for choosing a particular corporate form appears determinative" ignores the Federal Circuit's holding. *See* Edw. Br. at 19. The Federal Circuit expressly rejected consideration of the motivation for setting up the particular corporate form. *Poly-America*, 383 F.3d at 1311 ("[W]e do not speculate concerning the benefits that the two companies reap from dividing their operations and separating the owner of the patent from the seller of the patented invention[.]") The jury's award to Edwards of the lost profits of non-parties, in direct contravention of this Court's instructions, was erroneous and cannot be permitted to stand.

The damages award was infected by numerous additional errors, as set forth in Medtronic's Opening Brief and its briefs in support of its renewed JMOL motion. Rather than address the merits of the unjust award, Edwards suggests it be "viewed as a mandate from the jury." *See* Edw. Br. at 20. The award is not a "mandate"—it ignored the Court's clear instructions.

III. CONCLUSION

Medtronic respectfully requests a new trial if the Court does not enter judgment in Medtronic's favor.

Respectfully submitted,

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Dated: May 14, 2014